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510(k) SUMMARY
PhotoMedex, Inc.
XTRAC Excimer Laser System, Model AL7000

1. GENERAL

- *Submitter:* PhotoMedex, Inc.
  2431 Impala Drive
  Carlsbad, CA 92008

- *Contact Person:* Bob Rose
- *Date Prepared:* March 13, 2002

2. DEVICE NAME

- *Classification Name:* Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR §878.4810)

- *Common or Usual Name:* XeCl excimer laser

- *Trade or Proprietary Name:* XTRAC Excimer Laser System, model AL7000

3. PREDICATE DEVICES

Ultraviolet Phototherapy Systems

- HOUVA II, Phototherapy System, National Biological Corporation, 510(k) number: K885026
- UviSol, Phototherapy System, National Biological Corporation, 510(k) number: K934808
  DermaClear UV-B Phototherapy System, Coherent Star/Lumenis 510(k) number K011197

Excimer Laser

- XTRAC Excimer Laser System, model AL7000, PhotoMedex, Inc., 510(k) numbers: K992914, K003705, and K011382

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4. DEVICE DESCRIPTION

The XTRAC Excimer Laser System is a complete self-contained compact UV laser light source, which utilizes a XeCl gas mixture to generate an operator selected dose- and target-specific ultraviolet light at wavelength of 308 nm. The laser system consists of a keypad and display, a fiberoptic delivery system, a handpiece and a foot-switch. The laser is enclosed in a protective interlocked housing.

5. INTENDED USE

The intended use is targeted UVB phototherapy for psoriasis, vitiligo, atopic dermatitis, and non-autoimmune based leukoderma of affected skin.

6. SUBSTANTIAL EQUIVALENCE

The application of the XTRAC Excimer Laser System has been proven to be substantially equivalent to current legally marketed devices in the treatment of vitiligo via K003705. In that application, PhotoMedex demonstrated that narrow-band UV-B 311 alone had been shown to be just as effective in the treatment of vitiligo as PUVA (Westerhof and Nieuweboer-Krobotova[4]). The authors in this study concluded, "the treatment of vitiligo with narrow-band UV-B twice weekly is a safe and effective treatment." Vitiligo, which is recognized as a cosmetic problem, is a form of leukoderma.

Current published data supports narrow-band UVB (utilizing ultraviolet lamp sources) to be effective in the regimentation of skin which has been affected by leukoderma such as the latent hypopigmentation, which is frequently experienced in complications resulting from carbon dioxide lasers used for skin resurfacing.

The intended use for the PhotoMedex XTRAC Excimer Laser System is within the scope of the predicate ultraviolet lamps. Both device types share the same methods and mechanisms (UVB light) to produce a result for the purpose of dermatological phototherapy.

The XTRAC Excimer Laser System, model AL7000 is currently market cleared for other skin conditions where UVB phototherapy has shown to be safe and effective via 510(k) numbers K992914, K003705, and K011382.

[4] Westerhof W, Nieuweboer-Krobotova L. Treatment of vitiligo with UV-B radiation vs topical psoralen plus UV-A. Arch Dermatol 1997, 133:1525-1528.

7. CLINICAL PERFORMANCE TESTING

Verification and validation to substantiate inclusion of the indication of UVB phototherapy for the treatment of leukoderma by the AL7000 is supported in a clinical study[5] which utilized a 308nm excimer laser to successfully induce repigmentation on subjects. These subjects had experienced hypopigmentation (leukoderma) as a result of carbon dioxide laser resurfacing, and confirmed a 50% to 75% improvement or greater in treating leukoderma.

8. PRODUCT PERFORMANCE TESTING

Testing conducted on the XTRAC Excimer Laser System includes conformance to all relevant international EN 60601 series of standards, 21 CFR Part 1040.10 & 1040.11 Performance Standards for Light-Emitting Products and is a UL 2601 classified device.

9. CONCLUSIONS

Based on the same intended use as UVB sources for phototherapy, the previously cleared technological characteristics of the XTRAC Excimer Laser (which are unchanged to support this additional indication), and the performance data, PhotoMedex believes that the XTRAC Excimer Laser System is substantially equivalent to the predicate devices.

[5] Friedman. Paul MD, Geronemous, Roy MD, Use of the 308-nm Excimer Laser for Postresurfacing Leukoderma, *ARCH DERMATOL*, vol. 137, June 2001, 824-825.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2002

Mr. Bob Rose
Director of Regulatory Affairs
and Quality Assurance
Photo Medex, Inc.
2431 Impala Drive
Carlsbad, CA 92008

Re: K020847
Trade/Device Name: XTRAC Excimer Laser System, Model AL7000
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 13, 2002
Received: March 15, 2002

Dear Mr. Rose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020847

Device Name: ***XTRAC Excimer Laser System, model AL7000***

Indications for Use:

UVB Phototherapy for psoriasis, vitiligo, atopic dermatitis, and leukoderma

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020847